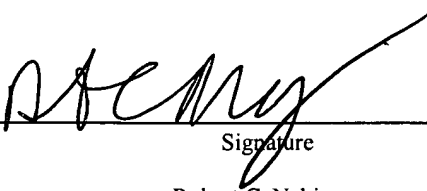




FISH & RICHARDSON P.C.

PTO/SB/33 (07-05)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number: 00216-091011
I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop AF, Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450. _____ Date of Deposit _____ Signature _____ Typed or Printed Name of Person Signing Certificate	Application Number 10/663,352	Filed September 15, 2003
	First Named Inventor Mingchih M. Tseng et al.	
	Art Unit 1614	Examiner Frederick Krass
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a Notice of Appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record <u>33,431</u> (Reg. No.)</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p>		
		 _____ Signature Robert C. Nabinger _____ Typed or printed name (617) 542-5070 _____ Telephone number November 2, 2005 _____ Date
<input type="checkbox"/> Total of no. forms are submitted.		



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Mingchih M. Tseng et al. Art Unit : 1614
Serial No. : 10/663,352 Examiner : Frederick Krass
Filed : September 15, 2003
Title : COLOR CHANGING MATRIX AS WEAR INDICATOR

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REMARKS SUBMITTED WITH PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 45-52 are pending. Claim 45 is the only independent claim; it reads as follows:

45. A color-changing matrix comprising a layer including a mixture of a water-insoluble polymer, a water-soluble polymer, and a water-leachable colorant that leaches from the matrix when the matrix is exposed to water to provide a change in color.

Claim 45 thus is directed to a "color-changing matrix" including "a layer" comprising a "mixture" of three ingredients -- a water-insoluble polymer, a water-soluble polymer, and a water-leachable colorant.

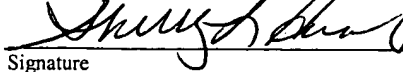
Claim 45 has been rejected under 35 U.S.C. § 102(b) in view of Barclay et al., U.S. Pat. 5,021,053 ("Barclay"). According to the Examiner, Barclay describes an osmotic delivery device including an outer layer containing a water-insoluble polymer (polystyrene) and an inner layer including a water-soluble polymer and a drug that qualifies as a water-leachable colorant. The Examiner contends that the combination of the outer layer and inner layer in Barclay's device provide the "layer" required by claim 45. The Examiner further contends that the polystyrene in the outer layer and the water-soluble polymer and drug in the inner layer are a "mixture."

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November 2, 2005

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Signature

Sherry L. Hunt

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Applicants do not agree with the Examiner's interpretation of "layer", but for purposes of this review will focus on the term "mixture". Claim 45 relates to a chemical composition -- a composite -- in which three chemical components (water-insoluble polymer, water-soluble polymer, and water-leachable colorant) are mixed together. But the Examiner, to give claim 45 a sufficiently broad scope to encompass the device described by Barclay, adopts definition 2(b) of mixture from Webster's Ninth New Collegiate Dictionary:

1(a): the act, the process, or an instance of mixing **(b1):** the state of being mixed **(b2):** the relative proportions of constituents; specif: the proportion of fuel to air produced in a carburetor **2:** a product of mixing: COMBINATION as **a:** a portion of matter consisting of two or more components in varying proportions that retain their own properties **b:** a fabric woven of variously colored threads **c.** a combination of several different kinds. (Emphasis original).

The Examiner made a clear error in relying on definition 2(b), which on its face relates to fabrics made from multiple threads. Claim 45 does not relate to fabrics or threads, but rather to chemical compositions including multiple ingredients. Definition 2(a) is the definition that plainly applies to chemical compositions -- a "product of mixing: COMBINATION as **a:** a portion of matter consisting of two or more components in varying proportions that retain their own properties."

Applicants understand that claims should be given "their broadest reasonable interpretation consistent with the specification" during prosecution. See In re Hyatt, 211 F.3d 1367, 1372 (Fed. Cir. 2000). But the Court of Appeals for the Federal Circuit has repeatedly emphasized that this doctrine does not relieve the Examiner from the responsibility of interpreting claim language in light of the specification from the standpoint of a person of ordinary skill in the art. See, for example, Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir. 1997), where the Court reasoned:

During the patent examination process, claims receive their broadest reasonable meaning.... However, this does not relieve the PTO of its essential task of examining the entire patent disclosure to discuss the meaning of claim words and phrases.

See also In re Bond, 910 F.2d 831, 833 (Fed. Cir. 1999) (during prosecution "claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art") (emphasis in original).

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Attorney's Docket No.: 00216-091011 / OB-37H

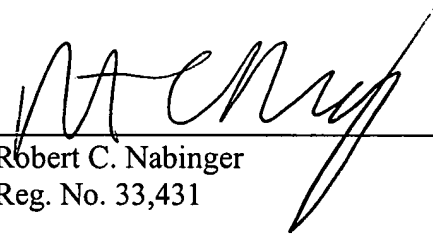
The present application does not relate to the fabric art. Instead, the application describes and claims a chemical composition. A person of ordinary skill in the art, reading the application, would understand all this and also would understand that definition 2(a) from Webster's Dictionary is the applicable definition.

With the term mixture properly interpreted, the 35 U.S.C. § 102(b) rejection based on Barclay evaporates, and the pending claims should be allowed.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: November 2, 2005



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